Food Safety Legislation

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Agenda

- How we got here
- Overview of H.R. 2749 The Food Safety Enhancement Act of 2009
 - New responsibilities for companies
 - Increased oversight of imports
 - New enforcement authorities
 - Fees
- What's next
- Key Differences in S. 510



How We Got Here

- Series of high profile food safety outbreaks
- Food manufacturing standards in the FFDCA date back to 1906
- Strong support from the Obama Administration



		US ADMINISTRATION	N UT REPERSY
60 Eighth Street NE			/09/2009 - 01/27/2009*
Atlanta, GA 30309		FUER	Area Area area area area area area area
(404) 253-1161 Fax: (404) 253-1202			36857
Industry Info	station: www.fds.gov/oc/ind	ustry	
	Lightsey, Plant Operations		
Peanut Corporation Of America 14075 b		14075 Magnolia	St
Blakely, GA			
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DURING AN INSPEC	CTION OF YOUR FIRM WE OBSERVED:		
OBSERVATION	1		
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What's Coming

- July 2009, the U.S. House of Representatives passed H.R. 2749, the Food Safety Enhancement Act of 2009
 - New responsibilities for companies
 - Increased oversight of imports
 - New enforcement authorities
 - Fees



Food Industry Responsibilities



- Food Safety Plans
- Food Defense Plans
- Performance standards
- Full records access
- Traceability
- Reporting requirements
- Not to be forgotten
 - Annual registration
 - Risk-based inspections
 - Safety standards for fruits, vegetables, and nuts



To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2009

Mr. DINGHLL (for himself, Mr. WAXMAN, Mr. PALLONE, Mr. STUFAR, Ms. DEGerrer, and Ms. SUTTON) introduced the following bill which was referred to the Committee on Energy and Commerce

A BILL

- To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.
- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Food Safety Enhance-
- 5 ment Act of 2009".
- 6 SEC. 2. TABLE OF CONTENTS.
- 7 The table of contents of this Act is as follows:
 - Sec. 1. Short title.
- Sec. 2. Table of contents. Sec. 3. References.
- Sec. 4. Rule of construction

- COOL

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Food Safety Plans

- Conduct hazard analysis
- Identify and implement preventive controls
 - To prevent, eliminate, or reduce hazards to an acceptable level
 - Those controls a person knowledgeable about safe manufacturing, processing, packing, transporting, holding of food would employ
 - Consistent with current scientific understanding
- Validate food safety plan
- Monitor and verify performance
- Take corrective and preventive actions as needed
- Keep records
- FDA can establish preventive controls by product type

Food Defense Plans



- Identify hazards that may be intentionally introduced
- Implement preventive measures to minimize risk of intentional contamination
 - Processing security
 - Cybersecurity
 - Material security (ingredients, finished product, packaging)
 - Personnel security
 - Storage security
 - Shipping and receiving security
 - Utility security
- Check that measures are in place and working; periodically test plan
- Maintain records of checks, corrective actions, assessment activities

Oversight of Imports

- Foreign facilities subject to all the same requirements as U.Sbased facilities
- FDA authority to require third party certification for food safetyrelated reason
- Accredited laboratory must be used for import testing
- Importers and customs brokers required to register
- Good importer practices
 - Including supply chain verification procedures
- Tighter control over import entry filings
- Expedited entry at border if safety and security guidelines met





Enforcement Authorities

- Civil money penalties
- Increased criminal penalties
- Suspension of registration
- Mandatory recall
- Quarantine
- Expanded administrative detention authority
- Subpoena power
- Prohibition on false or misleading reports
- Prohibition on delaying or refusing an inspection







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Fees

- Registration Fee
 - \$500 per facility
 - \$175,000 cap per company
- Registration fee for importers (but not customs brokers)
 - \$500
- Reimbursement to FDA for
 - Re-inspections
 - Recall
- Export certificates







Next Steps

- · Senate expected to take up a bill this fall
- President Obama will likely sign



How Does a Bill Become a Law?



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Key Differences in S. 510

- Traceability
- Records Access
- Mandatory recall authority
- Foreign supplier verification program
- Third party certification
- No registration fee
- Fewer enforcement authorities
- No COOL

111TH CONGRESS 1ST SESSION

> To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

S. 510

IN THE SENATE OF THE UNITED STATES

MANCH 3, 2009

Mr. DURISIN (for himself, Mr. GREGG, Mr. KRENNEDY, Mr. BURE, Mr. DODD, Mr. ALEXANDERS, and Mr. ISANSCOO) introduced the following bill, which was read twice and referred to the Committee on Health, Education, Labor, and Persions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

1 Be it enacted by the Senate and House of Representa-

2 tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-

TENTS.

4

5 (a) SHORT TITLE.—This Act may be cited as the

6 "FDA Food Safety Modernization Act".

7 (b) REFERENCES.—Except as otherwise specified,

8 whenever in this Act an amendment is expressed in terms

9 of an amendment to a section or other provision, the ref-



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Down the Road

- Various effective dates for different provisions
- Some provisions require FDA fact-finding and new regulations
- Longer implementation time for small and very small **businesses**







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